IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	)	Master Docket: Misc. No. 2:21-1230
	)	MDL No. 3014
This Document Relates To:	)	
Dix v. Philips North America, LLC, et al.	)	**JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Robert Dix, by and through his undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), Philips Holding USA, Inc. ("PHUSA"), and Philips RS North America LLC ("Philips RS") (collectively referred to as "Philips" or the "Defendants") and alleges the following upon personal knowledge and belief, and investigation of counsel:

INTRODUCTION

1. Philips manufactures, markets, sells, and distributes a variety of products for sleep and home respiratory care.

2. Philips manufactures, markets, imports, sells, and distributes a variety of Continuous Positive Airway Pressure (CPAP) and Bilevel Positive Airway Pressure (Bilevel PAP) devices for patients with obstructive sleep apnea ("OSA").

3. Philips also manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

4. On June 14, 2021, Philips issued a recall notification for many of its CPAP and Bilevel PAP devices as well as a number of its ventilator devices.

5. In its recall notification, Philips advised of potential health risks related to the sound abatement foam used in the affected devices.

6. Philips informed patients using these affected devices of potential risks from exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.

7. Specifically, Philips notified patients that the risks related to issues with the sound abatement foam include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects.

8. Plaintiff Robert Dix was prescribed the use of and purchased one of Philips' recalled devices, a Respironics Dream Station Auto C-PAP to treat his obstructive sleep apnea in Spring of 2016.

9. Plaintiff used Philips' Respironics Dream Station Auto C-Pap device bearing Serial Number J168712740034, Model Number DSX500H11 (the "subject device"), one of Philips' recalled devices, on a daily basis for a number of years.

10. In or around December 2019, Plaintiff was diagnosed with lung cancer.

11. As a direct and proximate result of Philips' conduct, Plaintiff has suffered serious and substantial life-altering injuries.

12. As a direct and proximate result of the subject device, manufactured, marketed, imported, sold, and distributed by Philips, Plaintiff has suffered physical, emotional, and financial injuries, including lung cancer.

PLAINTIFF

13. Plaintiff Robert Dix is an adult resident and citizen of Prairie Village, Kansas. Prairie Village, Kansas is located in Johnson County.

14. Plaintiff was prescribed the use of the subject device while a resident of Johnson County, Kansas, he purchased the subject device in Kansas, and the majority of his use of the subject device occurred in Kansas.

DEFENDANTS

15. Defendant Koninklijke Philips N.V. ("Royal Philips") is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips NA and Philips. Royal Philips can be served with process via the *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters* ("Hague Service Convention").

16. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is PHUSA, which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA may be served through its registered agent, Corporation Service Company, at 2900 SW Wanamaker, Suite 204, Topeka Kansas 66614.

17. Defendant Philips Holding USA, Inc. ("PHUSA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is the sole member of Defendant Philips NA. PHUSA may be served through its registered agent Corporation Service Company at 251 Little Falls Drive, Wilmington, New Castle, Delaware 19808.

18. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.1 Philips RS may be served through its registered agent, Corporation Service Company, at 251 Little Falls Drive, Wilmington, New Castle, Delaware 19808.

19. Royal Philips, Philips NA, PHUSA, and Philips RS are hereinafter collectively referred to as "Philips" or the "Defendants."

JURISDICTION AND VENUE

20. At all times pertinent to this Complaint, Defendants were and are in the business of designing, manufacturing, marketing, promoting, advertising, and selling devices for the treatment of obstructive sleep apnea, including the Respironics Inc. "Dream Station" Auto CPAP, bearing Serial Number J168712740034, Model Number DSX500H11, purchased by Plaintiff at issue in this lawsuit (the "subject device").

21. At all times pertinent to this Complaint, Defendants were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist. Defendants operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and

funds, disregarded corporate formalities, and used each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and/or tort liability.

22. At all times pertinent to this Complaint, Defendants acted in all respects as agents or apparent agents of one another.

23. At all times pertinent to this Complaint, Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising, and selling of devices for the treatment of obstructive sleep apnea, including the subject device. Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other, rendering them jointly liable to Plaintiff.

24. Defendants regularly transact business in Kansas that includes marketing and selling devices for the treatment of obstructive sleep apnea, derive substantial revenue from their business transactions in Kansas, and have purposely availed themselves of the privilege of doing business in Kansas.

25. Defendants shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to Kansas through the stream of commerce.

26. Defendants' actions in marketing and selling their devices in Kansas should have led them to reasonably anticipate being hauled into Court in Kansas.

27. Defendants have sufficient "minimum contacts" with Kansas that subjecting them to personal jurisdiction in Kansas does not offend traditional notions of fair play and substantial justice.

28. As detailed below, Plaintiff suffered injuries in Johnson County, Kansas from the subject device that Defendants negligently designed and/or manufactured either in Kansas or

outside of Kansas. Thus, Defendants committed a tort either in Kansas or outside of Kansas that caused injuries in Kansas, and the Court has personal jurisdiction over Defendants under Kansas's Long Arm Statute, Kan. Stat. Ann. § 60-308.

29. This Court has personal jurisdiction over Philips NA, PHUSA, and Philips RS because of their systematic and continuous contacts with Kansas as well as their maintenance of a registered agent for service of process in Kansas.

30. This Court has personal jurisdiction over Royal Philips because of its systematic and continuous contacts with Kansas.

31. This Court has original jurisdiction in this matter pursuant to 28 U.S.C. §1332(a)(1) and §1332(a)(2), as there is complete diversity between Plaintiff and Defendants and the amount in controversy exceeds $75,000.

32. There is complete diversity between Plaintiff and all of the members comprising Philips NA and Philips RS.

33. This Court is a proper venue for this civil action pursuant to 28 U.S.C § 1391(b)(2) as the event giving rise to the Plaintiff's claims occurred in Johnson County, Kansas.

34. This Court's exercise of personal jurisdiction over Defendants comports with due process.

BACKGROUND

35. At all relevant times, Defendants manufactured, marketed, sold, and distributed a lineup of CPAP and BiPAP devices as well as ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing, and other respiratory conditions, including sleep apnea.

36. Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Recalled Devices, including the subject device used by Plaintiff, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review of safety or efficacy is required.

A. Continuous Positive Airway Pressure Therapy

37. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a nasal or facemask device and a CPAP device helps individuals breathe by increasing the air pressure in an individual's throat.

38. Sleep Apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

B. Bi-Level Positive Airway Pressure Therapy

39. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP is distinguishable from CPAP therapy, however, because BiPAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

C. Philips' Sleep & Respiratory Care Devices Were Endangering its Users

40. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR "sound abatement" foam Philips used to minimize noise in several CPAP and BiPAP respirators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone [], and certain environmental conditions involving high humidity and temperature."[1]

[1] *First Quarter Results*, PHILIPS (Apr. 26 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf (accessed June 30, 2021).

41. Philips has utilized polyester-based polyurethane (PE-PUR) sound abatement foam to dampen device vibration and sound during routine operation.

42. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices.[2]

43. In its recall notification, Philips identified examples of potential risks which include exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.[3]

44. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.[4]

45. According to Philips' recall notice, the PE-PUR Foam used in Recalled Devices puts Recalled Device users at risk of suffering from the following health harms: "*Particulate exposure* can cause headache, irritation [skin, eye, and respiratory tract], inflammation, respiratory issues, and possible toxic and carcinogenic effects[;]" whereas the "potential risks of *chemical exposure due to off-gassing* include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and *carcinogenic* effects."[5]

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[2] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed June 30, 2021).

[3] *Philips issues recall notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (accessed June 30, 2021) (emphasis added).

[4] *Id.*

[5] *Philips issues recall notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-

46. On June 14, 2021, Philips also issued a brief report titled "Clinical Information for Physicians." In this report, Philips disclosed that "[l]ab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

-Toluene Diamine

-Toluene Diisocyanate

-Diethylene glycol."[6]

47. In its report titled "Clinical Information for Physicians," Philips also disclosed that lab testing performed by and for Philips has also identified the presence of Volatile Organic Compounds (VOCS) which may be emitted from the sound abatement foam component of the affected devices. "VOCs are emitted as gases from the foam included in the [affected devices] and may have short- and long-term adverse health effects. Standard testing identified two compounds of concern may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

-Dimethyl Diazine

-Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)- "[7]

D. Philips' Recalled Devices

health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (accessed June 30, 2021) (emphasis added).

[6] *Sleep and Respiratory Care update, Clinical information for physicians*, PHILIPS (June 14, 2021), https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf?_ga=2.43039205.1759564883.1625006706212130326.1624473291&_gl=1*2nhu1w*_ga*MjEyMTMwMzI2LjE2MjQ0NzMyOTE.*_ga_2NMXNNS6LE*MTYyNTE1MTQ3MC4xNi4xLjE2MjUxNTE1OTUuMTg. (accessed June 30, 2021).

[7] *Id.*

48. In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.[8]

49. The list of the devices recalled by Phillips (the "Recalled Devices") includes:

Philips CPAP and Bilevel PAP Devices Subject to Recall[9]	
Device Name/Model	**Type**
Philips E30 (Emergency Use Authorization)	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips DreamStation ASV	Continuous Ventilator, Non-life Supporting
Philips DreamStation ST, AVAPS	Continuous Ventilator, Non-life Supporting
Philips SystemOne ASV4	Continuous Ventilator, Non-life Supporting
Philips C Series ASV, S/T, AVAPS	Continuous Ventilator, Non-life Supporting
Philips OmniLab Advanced Plus, In-Lab Titration Device	Continuous Ventilator, Non-life Supporting
Philips SystemOne (Q Series)	Non-continuous Ventilator
Philips DreamStation, CPAP, Auto CPAP, BiPAP)	Non-continuous Ventilator
Philips DreamStation GO, CPAP, APAP	Non-continuous Ventilator
Philips Dorma 400, 500, CPAP	Non-continuous Ventilator
Philips REMStar SE Auto, CPAP	Non-continuous Ventilator

Philips Mechanical Respirator Devices Subject to Recall[10]	
Philips Device Name/Model	**Type**
Philips Trilogy 100 Ventilator	Continuous Ventilator
Philips Trilogy 200 Ventilator	Continuous Ventilator

[8] Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due-health-risks-n1270725 (accessed June 29, 2021).
[9] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed June 30, 2021).
[10] *Id.*

Philips Garbin Plus, Aeris, LifeVent Ventilator	Continuous Ventilator
Philips A-Series BiPAP Hybrid A30	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP V30 Auto Ventilator	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP A40	Continuous Ventilator, Non-life Supporting
Philips A-Series BiPAP A30	Continuous Ventilator, Non-life Supporting

50. Philips issued the following advice to patients using any of the Recalled Devices:

- "For patients using Bilevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."[11]
- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."[12]

E. Philips Unreasonably Delayed its Recall

51. Defendants have not disclosed when they first received reports from users of its Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[13] However, given how long ago the first of the Recalled Devices came to market, it is unlikely that Defendants only recently learned of these issues.

52. Thus, as a result of user reports and other testing performed by and on behalf of Defendants, Defendants were aware of the degradation of the PE-PUR sound abatement foam used

[11] *Id.* (emphasis in original).
[12] *Id.* (emphasis in original).
[13] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed June 30, 2021).

in the Recalled Devices, yet continued to manufacture, market, and sell the Recalled Devices with such awareness for a significant period of time. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of developing adverse health effects, including cancer.

PLAINTIFF ROBERT DIX

53. On or around March 2016, Plaintiff was prescribed the use of and purchased Philips' Respironics Dream Station Auto C-Pap device bearing Serial Number J168712740034, Model Number DSX500H11 (the "subject device"). The subject device prescribed for and purchased by Plaintiff was one of the Recalled Devices.

54. At the time Plaintiff was prescribed the use of and purchased the subject device, he was a resident and citizen of Johnson County, Kansas.

55. Starting in 2016 for several years, Plaintiff used the subject device daily to treat his sleep apnea.

56. At all times Plaintiff used the subject device, he used the subject device in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

57. At all times Plaintiff used the subject device, he used the subject device for a purpose for which the subject device was marketed, designed, and intended.

58. At all times Plaintiff used the subject device, he used the subject device in accordance with the directions and instructions issued by his physician who prescribed the use of the subject device.

59. After, and as a result of using the subject device, Plaintiff has suffered personal injuries including harm to his respiratory system, cellular damage, DNA damage, and lung cancer,

among others. These injuries would not have occurred but for the defective nature of the subject device and/or Defendants' wrongful conduct.

60. Plaintiff was diagnosed with lung cancer in December 2019.

61. Plaintiff's use of the subject device caused or significantly contributed to his development and progression of lung cancer, which has permanently changed his life.

62. By reason of the foregoing, Plaintiff has had to undergo significant treatment, including a lobectomy, and will be required to undergo significant treatment in the future, and now requires constant and continuous medical monitoring and treatment due to the defective nature of the subject device and/or Defendants' wrongful conduct.

63. As a result of the aforesaid conduct and the subject device manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff was injured, resulting in severe mental and physical pain and suffering. Such injuries will result in some permanent disability for his person. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages should be awarded.

CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

64. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

65. Plaintiff pleads this count under Kansas's strict liability provision, Kan. Stat. Ann. §60-3301 et. seq.

66. At all times herein mentioned, Defendants were engaged in the business of manufacturing and/or selling the Recalled Devices, including the subject device.

67. The subject device was and is in a defective condition and unreasonably dangerous to persons who might be expected to use the product.

68. The subject device was in a defective condition at the time it left control of Defendants.

69. The subject device was expected to reach and did reach the hands of the plaintiff and his physician without substantial change in the condition in which it was manufactured and/or sold.

70. The subject device is defective in design because it causes headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects. It is more dangerous than other available devices indicated for similar conditions and uses, and the utility of the device does not outweigh its risks.

71. The defect in the subject device was the cause or contributed to cause plaintiff's injuries or damages.

72. The subject device is defective in design because the PE-PUR foam comprising part of the device can degrade into particles that enter the device's air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, cancer. At or before the time the subject device was released on the market and/or sold to Plaintiff, Defendants could have designed the product to make it less prone to causing the above listed health harms, a technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the function of the device.

73. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could

Plaintiff have known that Defendants had designed, developed, and manufactured the subject device in a way as to make the risk of harm or injury outweigh any benefits.

74. The subject device is and was being used in a way which the Defendants intended at the time it was prescribed to Plaintiff.

75. Defendants had a duty to create a device that was not unreasonably dangerous for its normal, intended use and breached this duty.

76. Defendants knew or should have known that the Recalled Devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew or should have known that patients for whom the Recalled Devices would be used, such as Plaintiff, could be and would be affected by the defective design and composition of the devices.

77. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

78. As a direct and proximate result of Defendants' placement of the subject device into the stream of commerce and Plaintiff's use of the product as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

79. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

80. Plaintiff pleads this count under Kansas's strict liability provision, Kan. Stat. Ann. §60-3301 et. seq.

81. At all times herein mentioned, Defendants designed, developed, researched, tested, and knew or should have known about significant cancer risks with subject device.

82. At all times herein mentioned, Defendants advertised, promoted, marketed, sold, and distributed the subject device that was used by the Plaintiff.

83. The subject device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said device without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

84. Defendants each had an independent duty and continuing duty to warn the medical community and Plaintiff's physicians about the significance of the risks of cancer and other health harms with the subject device.

85. Plaintiff used the subject device in a manner intended and foreseeable by Defendants.

86. The subject device was defective due to inadequate warnings because Defendants knew or should have known that the product created a significantly increased risk of cancer, among other health impacts, and failed to warn the medical community and Plaintiff's physician of the nature of such risks.

87. Defendants omitted and downplayed the significantly increased risks of cancer and other health risks with the subject device that Defendants knew or should have known from previous testing and research even prior to subject device's FDA approval.

88. The subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's risk of cancer and other health risks.

89. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, Defendants knew that their deliberate omissions would cause physicians, including Plaintiff's physician, to prescribe the subject device without being able to adequately weigh the risk of device's risk of cancer and other health risks.

90. If Defendants would have properly warned about the subject device's cancer risk and/or other health harms, no reasonable physician, including Plaintiff's physician, would have recommended or prescribed the subject device because the potential benefits of weight loss are significantly outweighed by the risk of cancer and/or other harms.

91. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff's physician, would have prescribed the subject device and no consumer, including Plaintiff, would have purchased and/or used the subject device.

92. As a direct and proximate result of the subject device's defects as described herein, Plaintiff developed cancer, suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT III
STRICT LIABILITY – MANUFACTURING DEFECT

93. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

94. Plaintiff pleads this count under Kansas's strict liability provision, Kan. Stat. Ann. §60-3301 et. seq.

95. At all times herein mentioned, Defendants were engaged in the business of manufacturing the subject device.

96. At all times herein mentioned, Defendants were involved in researching, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

97. The subject device was expected to and did reach Plaintiff without a substantial change in its condition.

98. The subject device was in a defective condition at the time it left the control of the Defendants.

99. At all relevant times, the Recalled Devices, including the subject device, were defectively and improperly manufactured by Defendants.

100. The defect in the subject device was the cause or contributed to cause Plaintiff's injuries and damages.

101. The foreseeable risks of the subject device were known and could have been avoided.

102. Furthermore, the Recalled Devices, including the subject device, were defectively manufactured in that the PE-PUR foam comprising part of the devices can degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, cancer. Plaintiff and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens, and other deleterious components and contaminants when using the Recalled Devices.

103. As a direct and proximate result of the defective manufacture of the subject device, Plaintiff suffered and will continue to suffer damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT IV
NEGLIGENT DESIGN

104. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

105. At all relevant times, Defendants designed, marketed, tested, promoted, supplied, sold and/or distributed the Recalled Devices, including the subject device, in the regular course of business that Plaintiff consumed.

106. The subject device was designed and intended to be used as for the treatment of sleep apnea and other health issues.

107. At all relevant times, Defendants had a duty to use ordinary care in the design of the subject device so that it would be reasonably safe for the use it was intended, or which could be reasonably anticipated.

108. At all relevant times, Defendants had a duty to design the subject device in such a way that the subject device was reasonably safe for the ordinary consumer who possesses knowledge common to the community as to the product's characteristics.

109. Defendants knew or by the exercise of reasonable care, should have known, the use of the subject device was dangerous, harmful and injurious when used by Plaintiff and consumers in a reasonably foreseeable manner.

110. Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of the subject device.

111. Defendants breached their duty by failing to use reasonable care in the design of the subject device by designing the device such that PE-PUR foam inside the device could produce highly harmful particles and gasses that enter the device's airway leading to the user's respiratory system.

112. The subject device contained and produced chemicals and particles which can lead to headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and cancer, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would be victim to.

113. Defendants breached their duty when they failed to use commercially-feasible alternative designs to minimize these harms, including but not limited to designing products that prevented exposure to particles and off-gasses from PE-PUR foam, using a kind of noise and vibration reducing foam that did not possess these harmful qualities, using alternative methods of

noise vibration reduction, preventing foam particles and gasses from entering the airway of the product, among many other potential designs.

114. Defendants breached their duty by failing to use reasonable care by declining to include an expiration or best if "used by" date, which left open the potential for the devices' chemical and other properties to change in an even more harmful manner.

115. As a direct and proximate result of Defendants' negligent design, Plaintiff suffered and will continue to suffer damages for which he is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT V
NEGLIGENT FAILURE TO WARN

116. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

117. At all relevant times, Defendants designed, manufactured, and/or sold the Recalled Devices, including the subject device that Plaintiff used.

118. The Defendants knew or, by the exercise of reasonable care, should have known, the subject device was potentially dangerous to users.

119. Defendants had a duty to give adequate warning of such danger where injury to a user such as Plaintiff could be reasonably anticipated if an adequate warning was not given.

120. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of the subject device.

121. The Defendants knew or, by the exercise of reasonable care, should have known, that the Recalled Devices posed risks including headaches, irritation of the skin, eye, and

respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and cancer, among other harmful effects, as described herein, that were known and knowable in light of scientific and medical knowledge that was generally accepted in the scientific community at the time of design, manufacture, and distribution of the Recalled Devices.

122. The Defendants owed a duty to all reasonably foreseeable users to disclose the risks associated with the use of the subject device.

123. The Defendants breached their duty of care by failing to use reasonable care in providing adequate warnings to Plaintiff's physician, in the subject device's labeling and packaging, and through marketing, promoting, and advertising of the subject device.

124. At all relevant times, Defendants could have provided adequate warnings and instructions to prevent the harms and injuries set forth herein, such as providing full and accurate information about the Recalled Devices to physicians, to patients, in advertising, at point of sale, on the devices' instructions and inserts, and on the devices' labels.

198. A reasonable company under the same or similar circumstances would have warned and instructed them of the dangers.

199. Plaintiff was injured as a direct and proximate result of Defendants' failure to warn and instruct because he would not have used or purchased the subject device had he received adequate warnings and instructions that he could be exposed to toxic and carcinogenic particles and gasses that cause headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, toxic chemicals, and cancer.

200. Defendants' lack of adequate and sufficient warnings and instructions and its inadequate and misleading advertising, labeling, and instructions to physicians was a substantial contributing factor in causing the harm to Plaintiff.

201. Plaintiff demands judgment against Defendants for compensatory damages, pain and suffering, and punitive damages, medical monitoring to diagnose subject device induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
NEGLIGENT MANUFACTURING

202. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

203. The Defendants had a duty to use exercise reasonable care in the manufacturing, assembling, inspecting and packaging of the subject device.

204. The Defendants knew or, by the exercise of reasonable care, should have known, use of the subject device carelessly manufactured, assembled, inspected, and packaged was dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

205. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of the subject device improperly manufactured assembled, inspected, and packaged.

206. Without limitation, the Defendants breached their duty to exercise reasonable care in manufacturing, assembling, inspecting, and packaging the Recalled Devices by their:

- Failure to follow Good Manufacturing Practices ("GMPs").

- Failure to inspect/test the Recalled Devices during the manufacturing process;
- Failure to adequately determine/test the integrity of PE-PUR foam and its qualities, especially after the devices have aged.
- Failure to adequately determine/test the purity of airflow through the Recalled Devices' airway, especially after the devices have aged.

207. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality of their devices.

208. Plaintiff was injured as a direct and proximate result of Defendants' failure to use reasonable care in the manufacturing, assembling, inspecting, and packaging of the subject device as described herein.

209. The Defendants' negligent manufacturing, assembling, inspecting, and packaging of the subject device was a substantial factor in causing Plaintiff's harms.

210. Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, medical monitoring to diagnose subject device induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
NEGLIGENCE/GROSS NEGLIGENCE

211. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

212. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling, and distribution of the Recalled Devices, including the subject device.

213. Defendants knew or should have known that using the subject device created a significantly increased risk of cancer, among other health harms.

214. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Defendants designed and developed the Recalled Devices without thoroughly or adequately testing the devices;

b. Defendants sold the Recalled Devices without doing proper and sufficient tests to determine the dangers to the users.

c. Defendants failed to adequately and correctly warn the Plaintiff, the public, and the medical community, of the cancer risks associated with the Recalled Devices.

d. Defendants advertised and recommended the use of the Recalled Devices for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of cancer risks.

e. Defendants failed to exercise reasonable care in designing the Recalled Devices in a manner which was dangerous to the users.

f. Defendants negligently manufactured the Recalled Devices in a manner which was dangerous to the users.

215. Additionally, Defendants under-reported, underestimated, and downplayed the serious dangers of the Recalled Devices' association with cancer and other health harms.

216. Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning cancer risks.

217. Additionally, Defendants under-reported, underestimated, and downplayed the serious dangers of the Recalled Devices' association with cancer and other health harms.

218. Defendants negligently compared the safety risk and/or dangers of the subject device with other forms of treatment for sleep apnea and similar conditions.

219. Defendants also failed to warn Plaintiff, prior to actively encouraging the sale of the subject device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of cancer.

220. Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding *all* adverse side effects—namely cancer—associated with the use of the subject device.

221. Once Defendants gained additional information about the Recalled Devices' association with cancer, it failed to update its warnings and thereafter accompany the Recalled Devices with adequate warnings regarding cancer.

222. Despite the fact that Defendants knew or should have known that the Recalled Devices caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute, and/or sell the devices to physicians and patients, including the Plaintiff.

223. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

224. Defendants' negligence was the proximate cause of Plaintiff's cancer-related injuries, among many other health harms, which Plaintiff suffered and/or will continue to suffer.

225. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects that led to his lung cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

226. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses.

227. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VIII
NEGLIGENT MISREPRESENTATION

228. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

229. Defendants, in the course of their business transactions involved in selling the subject device, supplied false information for the guidance of Plaintiff's physicians in their care of Plaintiff in stating that the subject device was tested and safe and effective for treating sleep apnea.

230. Defendants in supplying the false information failed to exercise reasonable care or competence in obtaining or communicating the false information.

231. Plaintiff relied upon this information and Plaintiff is one of a group of persons for whose benefit and guidance the information is supplied.

232. As a result of Defendants' supply of false information, Plaintiff suffered damages.

233.

234. Defendants' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

235. Defendants' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of cancer were made or omitted with the intent to induce Plaintiff to rely upon those facts or omissions.

236. Plaintiff was unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of cancer until *after* he had been exposed to carcinogenic particles and gasses.

237. Plaintiff justifiably relied upon the false representations of Defendants.

238. Had Defendants reasonably and proposed provided adequate warnings of cancer and other serious injuries, such warnings would have been heeded and no healthcare professional, including Plaintiff's physician, would have prescribed the Recalled Devices and no consumer, including Plaintiff, would have purchased and/or used the Recalled Devices.

239. As a direct and proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including lung cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

240. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT IX
FRAUD

241. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

242. At all relevant times, Defendants designed manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or

otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Plaintiff.

243. Defendants made false and/or untrue representations about the subject device.

244. Such representations were of existing and material facts.

245. Defendants made representations regarding the safety of the Recalled Devices and the substantial health risks and/or benefits associated with using the devices, all the while knowing the representations to be false or untrue, or recklessly made such representations without knowledge concerning them.

246. Such representations made by defendants were intentionally made for the purpose of inducing the public, including Plaintiff and/or his physicians to act upon them.

247. Plaintiff reasonably relied and acted upon the representations made.

248. Plaintiff sustained damages by relying upon them.

249. Plaintiff justifiably relied to his detriment on Defendants' fraudulent statements. Had Plaintiff been adequately informed of the material facts concealed from him regarding the safety of the subject device, and not intentionally deceived by Defendants, he would not have acquired/purchased or used the subject device.

250. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorney fees.

COUNT X
FRAUD THROUGH SILENCE

251. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

252. The Defendants had knowledge of material facts Plaintiff did not have and which the Plaintiff could not have discovered by exercise of reasonable diligence;

253. The defendants were under an obligation to communicate the material facts to Plaintiff.

254. The defendants intentionally failed to communicate to the Plaintiff the material facts.

255. The Plaintiff justifiably relied upon the defendant to communicate the material facts to the Plaintiff.

256. Plaintiff sustained damages as a result of the defendants' failure to communicate this to Plaintiff.

COUNT XI
BREACH OF EXPRESS WARRANTIES

257. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

258. The Defendants, through their advertising, promotional materials, and labeling, expressly warranted and affirmed that the Recalled Devices were safe for their intended uses and for uses which were reasonably foreseeable.

259. Defendants' representations became a basis of the bargain.

260. Defendants made express warranties which extended beyond delivery of the Recalled Devices and expressly warranted for future performance of the devices. Defendants advertised, promoted, and labeled the Recalled Devices as being safe and effective for the treatment of sleep apnea.

261. At all relevant times, Defendants breached said express warranties in that the Recalled Devices were unsafe and caused cancer among other harms. Plaintiff foreseeably used the subject device without knowing of the harmful and substantial consequences to his health.

262. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

263. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Plaintiff and the rest of the public that used the devices.

264. In reliance upon the express warranties made by Defendants, Plaintiff acquired/purchased and used the subject device, believing the subject device conformed to Defendants warranty that the subject device was safe and effective for the treatment of sleep apnea.

265. Plaintiff notified Defendants of the breach.

266. As a direct and proximate result of Defendants' breach of their express warranties concerning the subject device, Plaintiff suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XII
BREACH OF THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

291. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

292. Defendants, at the time of contracting for the sale of the subject device, had reason to know of a particular purpose (sleep apnea) for which the subject device was sold for.

293. Plaintiff and Plaintiff's physicians relied on Defendants' skill and judgment to furnish the suitable subject device.

294. There was an implied warranty that the subject device would be fit for suitable use to treat sleep apnea.

295. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the Recalled Devices' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

296. Defendants touted the Recalled Devices as safe, despite knowingly having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

297. Defendants intended to make Plaintiff and the general public believe the Recalled Devices were safe.

298. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

299. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Plaintiff and the consuming public.

300. Plaintiff relied on Defendants' skill or judgment in selecting and purchasing the subject device.

301. In reliance upon these implied warranties as to the safety of the subject device by Defendants, Plaintiff acquired/purchased and used the subject device, believing that the subject device was inherently safe.

302. Plaintiff notified Defendants of the breach.

303. As a direct and proximate Defendants' warranties concerning the subject device, as described herein, Plaintiff suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XIII

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

304. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

305. At all relevant times Defendants have been a merchant in regard to the Recalled Devices they created and sold to consumers.

306. Defendants breached their implied warranty of merchantability since the Recalled Devices were defective when created and designed, and do not conform with the promises represented on their labels.

307. Defendants failed to comply with merchantability requirements, as the Recalled Devices do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

308. Beyond Defendants' own direct sales of the Recalled Devices, Plaintiff and other consumers are third-party beneficiaries of Defendants' agreements with its distributors, dealers, and sellers for the distribution, dealing, and sale of the Recalled Devices to consumers. Plaintiffs and consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled Devices are manufactured with the express and intended purpose of selling the devices to consumers.

309. As a direct and proximate result of Defendants' breach of their implied warranties of merchantability regarding the subject device, Plaintiff was damaged because, had he been aware of the unmerchantable condition of the subject device, he would have not acquired/purchased the subject device and not suffered injuries and damages from their use, for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XIV
VIOLATION OF THE KANSAS CONSUMER PROTECTION ACT

310. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

311. Plaintiff is a "consumer" as defined in the Kan. Stat. Ann. §50-624 (b) in that Plaintiff acquired/purchased, other than for purposes of resale, goods from the Defendants, for personal, family, or household purposes.

312. Defendants are "suppliers" as defined by Kan. Stat. Ann. § 50-624(l) in that Defendants are one or more of the following: manufacturer, distributor, dealer, seller, lessor, assignor, or other person who, in the ordinary course of business, solicits, engages or enforces consumer transactions, whether or not dealing with the consumer.

313. Defendants engaged in one or more deceptive business practices, as defined by Kan. Stat. Ann. 50-626, including but not limited to one of the following:

(a) Defendant represented to Plaintiff:

i. The Recalled Device was of a particular standard, quality, grade, style, or model which differed materially from the representation.

ii. The Recalled Device had characteristics, benefits, or qualities it did not have.

iii. The Recalled Device has uses, benefits, or characteristics it did not have.

(b) Willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact.

314. Plaintiff acted in reasonable reliance upon Defendants' Deceptive Business practices through Defendants' misrepresentations and omissions. Had Defendants not engaged in the deceptive conduct described herein, reasonable consumers and Plaintiff would not have

acquired/purchased the Recalled Devices if they had known the devices posed unreasonable and substantial risks to their health. Knowledge of these material factors would have highly impacted the Plaintiff's decision when first acquiring/purchasing and using the subject device.

315. As a direct and proximate result of the unlawful trade practices of Defendants, in violation of Kan. Stat. Ann. § 50-626, *et seq*., Plaintiff suffered and will continue to suffer damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, treble or per-violation damages, interest, costs, attorneys' fees, and all other damages cognizable under § 50-634.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants jointly and severally for damages, including punitive damages if applicable, to which he is entitled by law, as well as all costs of this action, interest and attorneys' fees, to the full extent of the law, whether arising under the common law and/or statutory law, including:

a. Judgment for Plaintiff and against Defendants;

b. Damages to compensate Plaintiff for his injuries, economic losses and pain and suffering sustained as a result of the use of Defendants' subject device;

c. Pre and post judgment interest at the lawful rate;

d. Punitive damages, if applicable, on all applicable Counts as permitted by the law;

e. A trial by jury on all issues of the case;

f. An award of attorneys' fees; and

g. For any other relief as this Court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied, including but not limited to all reliefs prayed for in this Complaint and in the foregoing Prayer for Relief.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Respectfully Submitted,

/s/ Jamie A. Rodriguez

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ATTORNEYS FOR PLAINTIFF

/s/ Jamie A. Rodriguez

Attorney for Plaintiff

Dated: June 6, 2022

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was filed on June 6th, 2022, through the Court's CM/ECF system, which will send a notice of the electronic filing.

/s/ *Jamie Rodriguez*
Attorney for Plaintiff